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ABSTRACT

Legal, ethical, and procedural guidelines for the participation of mentally retarded people in research were solicited from 167 agencies, of which 67 responded. A variety of documents was cited by the respondents. The documents appeared to establish the outside limits of ethical practice but did not establish actual procedure. Furthermore, the documents tended to address research as broadly defined and did not emphasize guidelines for survey or statistical summary research as opposed to manipulative experimentation. The issue of direct benefit of research to mentally retarded subjects as a condition for participation is examined with the review of research proposals, participant consent, and the use of substitute decision-makers for persons judged incompetent. (Author/CM)

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Agency Endorsement of Research Ethics

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Running head: Research ethics

Abstract

Legal, ethical, and procedural guidelines for the participation of mentally retarded people in research were solicited from 167 agencies, of which 67 responded. A variety of documents was cited by the respondents. The documents appeared to establish the outside limits of ethical practice but did not establish actual procedure. Furthermore, the documents tended to address research as broadly defined and did not emphasize guidelines for survey or statistical summary research as opposed to manipulative experimentation.

Agency Endorsement of Research Ethics

Recent years have witnessed a proliferation of guidelines and regulations for the conduct of research with human subjects. This development has been due in part to previous abuses of participants in research projects and increased concern for human rights, particularly of handicapped and other vulnerable groups. Mentally retarded individuals, by virtue of their cognitive limitations and likelihood of placement in various institutional settings, have been recognized as a particularly vulnerable group. As a result, research involving mentally retarded individuals is potentially subject not only to regulations pertaining to human research in general but also to guidelines developed especially with them in mind, in recognition of the unique ethical problems that may arise in research with mentally retarded subjects.

Although increased concern with ethical safeguards in research was long overdue, one wonders whether a consensus has emerged from the multitude of attempts to define ethical research practices. What bodies have developed and promulgated research guidelines? Have certain bodies and particular documents containing research guidelines taken precedence over others and dominated decision-making about research projects? Do different documents disagree about

what is and is not ethical research practice with mentally retarded individuals?

The present paper examines these questions, based on a survey of a wide range of organizations and agencies of potential relevance to mental retardation research. At a general level, the paper sheds some light on the state of the art in research ethics as it affects the wide range of research projects that are or might be conducted with mentally retarded participants. At a more specific level, part of the purpose of the survey was to estimate the difficulties that would be encountered in conducting a national survey of retarded citizens that would require gaining access to them through local agencies whose policies regarding confidentiality, release of information, consent, and research participation might vary widely.

METHOD

A letter of request was sent to 167 agencies considered likely to have an interest in the welfare of mentally retarded people. A variety of materials and mailing lists were drawn upon to compose a broad sampling of agencies and organizations involved in service to mentally retarded people or in the development of ethical standards for research. All 50 state departments in charge of mental retardation services were contacted, but the sample otherwise was unsystematic. The sample was designed

simply to elicit input from a wide range of sources in order to permit an analysis of the kinds of documents that emerged. The list included consumer organizations in the mental retardation field, professional associations, direct service agencies, accrediting bodies, governmental agencies, interest groups, commissions, foundations, and other agencies and organizations.

RESULTS AND DISCUSSION

AGENCY RESPONSES

Replies were received from 67 agencies, for a return rate of 40%. Responses fell into four categories: (a) documents relevant to the use of mentally retarded people as subjects in research; (b) references to, or endorsements of, such documents; (c) descriptions of procedures followed in approving or monitoring the use of mentally retarded people as subjects in research; and (d) letters of acknowledgment disclaiming involvement with research using mentally retarded people as subjects.

In the materials received from the 67 respondents, there were 129 citations of documents or procedures which pertained to the use of mentally retarded people as participants in research. Six respondents cited no regulations and no endorsement of others' regulations. Four respondents said they were in the process of developing guidelines and procedures otherwise undescribed.

Categories of documents cited by at least one respondent are listed in Table 1. The percentage of the 129 citations accounted for by each category is provided, as is the number of specific documents which were judged to fall within each category. For three categories (locally developed materials, state laws, and review committees), number of documents is not given because the materials cited were either ephemeral, not readily available to the public, or so numerous and varied as to be beyond the scope of this paper to describe. Documents mentioned by at least one respondent are listed in Table 2.

Insert Tables 1 and 2 about here.

The total number of distinct documents cited or endorsed was 37, evidence in and of itself of considerable competition among different approaches to the protection of human subjects of research. Four DHEW regulations comprised the most often cited category of documents, with the 1977 regulation receiving the most citations (N=14) of any single document cited by the 67 respondents. After the 1977 DHEW document, the most commonly cited single documents were those of the American Association on Mental Deficiency and the Joint Commission for the Accreditation of Hospitals, each with six citations. Otherwise, no single

document received more than two citations or endorsements.

Based on these data, there would seem to be no single document or authority which has emerged as the preeminent source of guidance for a large number of organizations and agencies. Federal influence was found to be relatively heavy (36.5% of the citations fell into the three federal categories), but emerged from a variety of documents (N=20). State and local documents were a major source of guidance (28.7% of the citations) but were far more varied than the federal documents. Nine documents emerging from professional organizations (e.g., the research standards of the American Psychological Association) constituted 14% of the citations. But more than one-fifth of the citations were to documents which could not be categorized among these seemingly obvious authoritative sources of guidance in the use of mentally retarded participants in research.

THE AAMD GUIDELINES

The AAMD Consent Handbook (1977) can provide a starting point for addressing the issues of interest to the present investigation. Although some would argue that a mentally retarded individual, especially one who is a resident of an institution, must never be permitted to participate in research, this position is contrary to AAMD guidelines. The AAMD emphasis is not on the participation or nonparticipation of the subject, but on the conditions

of consent available to the subject. The AAMD position is that researchers should have access to information about the mentally retarded and that the need for formal consent procedures varies with the specific circumstances of the research. Under some circumstances, implied or informal consent is appropriate for mentally retarded subjects as well as for non-mentally retarded subjects. When the population at large is sampled randomly, consent to participate must be sought from retarded subjects only if it is sought from the non-retarded members of the sample.

Formal consent procedures become necessary when research entails risk or when participation in a research project is linked to the subject's status of mental retardation. The availability of mentally retarded people as captive subjects has led to their abuse in the past; therefore, if nonretarded individuals may fulfill the requirements of the research as satisfactorily as retarded individuals, the retarded should not be asked to participate. If the retarded subject is appropriate or necessary to the research, however, then he or she may be asked to consent to participate. But when the research involves risk, intrusiveness, or irreversible impact upon a mentally retarded subject, express, rather than implied, consent is required.

Special attention must be given to formal consent

procedures under four conditions: (a) when the information derived from the research might identify the subject or his/her family; (b) when the information might identify any other person; (c) when it is likely that unsought information will accompany the release of the sought-for information; and (d) when the information is constitutionally protected under the First Amendment of the Constitution. Safeguards and guarantees of privacy may reduce the need for rigorous consent procedures. The provision of direct or indirect services or benefits to the subjects may also temper the requirement for consent, although the provision of services or benefits need not be a condition of conducting the research.

The particular circumstances of the mentally retarded lead the AAMD to favor a definition of consent which includes three elements: capacity, information, and voluntariness. Emphasis upon the traditional concept of informed consent (i.e., consent on the basis of complete information) is judged to be an inadequate safeguard for the mentally retarded population, for whom capacity to understand and voluntariness pose special problems linked to the legal concepts of competence and incompetence. The AAMD does not assume incompetence among the retarded population (the legal assumption that a person is competent until shown not to be competent is a starting point for the

AAMD), but it does assume that those labeled mentally retarded are at potential risk in the research situation. Despite the legal definitions of competence and incompetence, then, the researcher should be guided by situational definitions: an individual declared incompetent by a court may well be capable of understanding and consenting to the situational demands of the research project in question, whereas one who is assumed to be competent under other circumstances may be incapable of consent to the research in question. Thus, a researcher should be bound by the decisions of his or her subjects and adhere as closely as possible to the subjects' own preferences, even if a substitute decision-maker (e.g., a parent or guardian) must provide the legally valid consent. In the case of the individual who has been declared legally incompetent, researchers should be bound by the decisions of the substitute decision-makers who, in turn, should attempt to make the decision which the retarded person is most likely to have made if he or she were competent.

ALTERNATIVE AND COMPLEMENTARY VIEWS

The AAMD guidelines cover most of the issues addressed by the other documents cited by the respondents, but there remain important differences among the documents. Since a variety of procedures might need to be used in order to adhere to a variety of standards, dissimilarity among the

documents could hinder the conduct of research unless the procedure to be adopted satisfied the most stringent standards likely to be encountered. Thus, the guiding principles of several of the other documents cited by the respondents are discussed as alternative or complementary views of ethical procedures in the use of mentally retarded persons as subjects in research.

THE DIRECT BENEFIT RULE. The AAMD guidelines do not demand that mentally retarded subjects of research receive a direct benefit as a condition of their participation, but there is some variation in other documents' treatment of this issue. The direct benefit issue is intertwined with the more basic issue of whether it is ever justified to use mentally retarded persons as subjects in research projects. The American Psychological Association research standards suggest that scientists should not be asked to limit research to areas of immediate benefit to human need, since other questions might be more useful to the ultimate solution of these problems. Other organizations' guidelines might agree with the APA position in general, but reaction to past exploitation of certain vulnerable classes of subjects (in particular, residents of institutions) has led to an increasing emphasis on population-specific research criteria. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research has

stated that groups of vulnerable subjects should no longer be overburdened by the demands of research and underbenefited by its results. The trend, then, may be toward the American Bar Association's (ABA) position that research must relate to mental retardation to use mentally retarded subjects, and toward the DHEW proposal of August, 1974, which would limit research with mentally retarded subjects to topics most likely to benefit the mentally retarded. For example, the American Nurses' Association (ANA) guidelines are in agreement with the DHEW proposal. The standards of the Joint Commission for the Accreditation of Hospitals (JCAH) recommend that research in institutions must be explained to the staff and that the research results must be implemented in the institution.

The increased emphasis upon direct benefit evolves from an increased awareness of the coercive nature of institutions and of the impaired capacity of the mentally retarded persons who reside within institutions to give informed consent to research procedures. Of the documents cited by the respondents, only one (the Willowbrook Consent Judgment) establishes an absolute bar to research using mentally retarded subjects. Given the history of abuse within the Willowbrook facility, the consent judgment attempted to fully protect the welfare of the plaintiff class by permitting no further research involving them.

Other documents simply argue more forcefully than the AAMD that informed consent is difficult to obtain within an institution with the result that attempts to assess risk and benefit may be dubious exercises.

An example of the latter position is the ABA contention that informed consent "in a free world sense" is probably impossible within an institution. Nevertheless, the ABA does not call for the abandonment of institutional research. Instead, it focuses upon the capacity of the institution to provide standard care despite the increased demands of research and, in order to assure such care, suggests that research should be conducted only in facilities which meet JCAH standards. In a similar vein, the APA recommends that if research participation interferes with the subject's standard program, the researcher must assure later provision of any lost benefits from that program. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research would allow research using institutionalized children as subjects only if the research relates to their mentally retarded status, if the majority of the children in the facility are not wards of the state, and if each child has an advocate, who presumably will attempt to maximize benefit and minimize risk in any procedure which is proposed. The APA recommends avoiding contact with

neighbors, relatives, and employers, who might not realize that the subject is mentally retarded or that the subject had lived in an institution. For such a study, the APA suggests restricting interviews to staff who already know the subject's status and obtaining permission from the subject before interviewing anyone about the subject.

PROBLEMS OF CONFIDENTIALITY AND UNSOUGHT INFORMATION. All documents emphasize the importance of maintaining the research subject's confidentiality, but they vary in the sort of problems cited in this regard. In particular, as compared to the AAMD guidelines, other documents address more specifically the problems of safeguarding against obtaining unsought information and unanticipated outcomes.

A procedure to safeguard subject confidentiality is suggested by the Child Welfare League of America: all data should be processed in a setting other than that in which the data were collected, and the original data should be destroyed. Almost all documents consider the use of aggregate data (in which individual subjects cannot be identified) of little danger to the confidentiality of the subject. Almost all consider any identification of subjects a higher risk procedure which, at the least, would need to be cleared by the appropriate review bodies.

Problems associated with obtaining unsought information and unanticipated outcomes are most

specifically addressed by the APA. In the experience of the APA, it is not uncommon for a researcher to acquire information about a subject which is irrelevant to the research problem; when this information is of a sensitive nature, the welfare of the subject may be at risk. Examples expecially relevant to interview studies include the discovery that a research subject uses drugs, carries a weapon, is suicidal, or is engaging in unhealthy or destructive behavior. Researchers, then, may well find themselves in possession of information about their subjects which, if disclosed, would violate the subjects' confidentiality, but which, if not disclosed, could lead to harm to the subjects or to others. The legal responsibility of the researcher to disclose or not to disclose such information may vary from state to state. The ethical responsibilities suggested by the APA include the need for researchers to counsel their subjects about the limits to confidentiality which may pertain. The United States Bureau of the Census, however, takes the stronger position that "trust should be backed by law"; agencies should not promise confidentiality unless they provide absolute protection for the subject's data.

The APA addresses two other matters of confidentiality which should be noted. First, care should be taken that the publication of results of research do not lead to the

identification of individuals. Identification is especially likely if the published material includes case material from identified institutions. Second, the confidentiality of the subject might be considered violated if the results of the research are uncomplimentary to the subject's valued groups. An example might be a study of attitudes which could lead to the conclusion that certain ethnic groups express more prejudice against the mentally retarded than do other ethnic groups.

REVIEW, CONSENT, AND SUBSTITUTE DECISION-MAKERS. The specifics of review of research proposals, the consent to participate in research, and the use of substitute decision-makers for persons judged incompetent are addressed variously by the documents in question.

The general character of review bodies is the same in most guidelines, with the typical case being the institutional review board. One variation, however, is to assign the review of research proposals to a group external to the institution. A rather common practice is to require a certain number of proposal reviewers to be lawyers, physicians, psychologists, or sociologists. A variation on that practice is the requirement that one member of the review committee be of a cultural group similar to that of the patient.

Virtually all organizations' guidelines call for the

use of a substitute decision-maker under some circumstances for subjects judged to be incompetent. Two sets of guidelines differ from the AAMD position primarily in arguing forcefully against such a procedures. The ABA position is that substitute consent should be used only in extremely rare circumstances and only when especially significant information will be obtained as a result. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research takes the position that substitute consent cannot override the silence of the subject if the research is of more than minimal risk and if the procedures are not of direct benefit to the subject.

IDEAL VERSUS ACTUAL PRACTICE

To a great extent, the documents endorsed by responding agencies provide an ideal toward which agencies might strive, rather than a description of reality. Agency endorsement of legal, ethical, or procedural documents does not necessarily imply that day-to-day practice mirrors the contents of the documents in every detail. Practices which differ substantially from agency to agency may nevertheless remain within the permissible limits of national policy or reflect equally well the general principles embodied in a code of ethics. What the law permits, it may not command: the legality of providing a researcher with a given bit of information, for example, does not imply that every agency

is capable of or even willing to comply with requests for such information. Research review boards presumably have the right to reject even good and risk-free research.

IMPLICATIONS

The documents provided by the respondents present a somewhat varied description of ideal conditions toward which researchers might strive. Some tentative conclusions may be stated regarding the potential effect of these guidelines on research practices in the mental retardation field, especially a national survey of mentally retarded persons.

The identification of clients from agency files probably would be considered a risky procedure which would need approval by research review bodies. Identification of associates of clients (e.g., relatives, employers, or neighbors) probably would be considered an even higher risk procedure, since these individuals would not necessarily have prior knowledge of the clients' status as mentally retarded. The deliberations of the research review boards in such cases would almost certainly be influenced by considerations of direct benefit, since the interviewing of clients or their associates could be stressful or disruptive of the client's standard program, could involve sensitive information, or could result in the disclosure of unsought and potentially damaging information. The use of

mentally retarded subjects, rather than nonretarded subjects, is obviously necessary in a survey concerning the lives of mentally retarded people. However, the benefits to each individual subject accruing from a national survey would likely be negligible; the potential benefit to the mentally retarded population as a whole is a matter of opinion, the direction of which would likely be a determining factor in the review committees' recommendations.

Although the primary problem in a national survey would be the initial access to the subject population, the variety of allowable consent procedures and the variation in interpretations of other ethical considerations would also pose problems. The Bureau of the Census is regarded as a model for procedures to protect the data which individuals provide them under the force of law. Other agencies, on the other hand, may intend to protect individual privacy and may be capable of such protection under most circumstances, but they may not be able to enforce the protection of their clients' confidentiality if they provide researchers not under their administrative control with identifiable information. Deliberate abuse of information gained for research may be extremely unlikely, but, whether deliberate or accidental, the potential for abuse exists.

The results of the survey suggest that there is a multitude of documents relevant to the use of mentally retarded persons as research participants and there is inconsistency among the documents. As a result there is a lack of clarity regarding permissible research practices. Under these conditions, the conservative view of client welfare, which virtually all professional groups recommend, would likely result in a refusal to release rosters of mentally retarded individuals to a national survey team. Further, more typical and smaller scale research would likely be made difficult as well.

FOOTNOTE

This paper was presented at the American Psychological Association Convention, Washington, D.C., August 25, 1982.

Table 1

Documents Cited by Survey Respondents

Category	Citations	Documents
DHEW	17.1%	4
Locally developed materials	16.3%	NA
Professional organizations	14.0%	9
State laws	12.4%	NA
Other federal executive branch	10.9%	7
Miscellaneous	9.3%	5
Other federal sources	8.5%	9
JCAH	4.7%	1
Review committees	4.7%	1
Consumer organizations	2.3%	2

Table 2

Documents Cited by Survey Respondents

Document	N
Locally developed materials.	21
State Laws.	16
United States Department of Health, Education, and Welfare. Code of Federal Regulations, 45 CFR 46, Protection of Human Subjects, 1977, revised edition.	14
American Association on Mental Deficiency. Statement on the Use of Human Subjects for Research.	6
Joint Commission for the Accreditation of Hospitals (standards).	6
No regulations and no endorsement of others' regulations.	6
Review committee approval (not otherwise endorsed).	5
In process of developing guidelines and procedures.	4
Miscellaneous (policies and procedures of facility, university, or funding source, and local laws; standards related to other issues; affirmative action, non-discrimination provisions, common sense).	4
United States Department of Health, Education, and Welfare. Protection of Human Subjects: Proposed Policy, 39 FR 18914, Vol. 39, No. 165, Pt. III, Aug-	

ust 23, 1974. 3

United States Department of Health, Education, and Welfare. Institutional Guide to DHEW Policy on Protection of Human Subjects, December 1, 1971. 3

United States Public Health Service. Policy and Procedure Order 129, as revised July 1, 1966. 3

American Association on Mental Deficiency. Consent Handbook. Washington, D.C.: Author, 1977. 2

American Bar Association. Statement before National Human Experimentation Group. Mental Disability Law Reporter, 1976, Sept.-Oct., 155-159. 2

American Psychological Association. Ethical Principles in the Conduct of Research with Human Participants. Washington, D.C.: Author, 1973. 2

Child Welfare League of America (standards). 2

National Association for Retarded Citizens. Guidelines for Biomedical and Pharmacological Research Procedures and the Protection of Human Subjects in Residential Facilities for Mentally Retarded Persons. 2

National Association of Social Workers. Code of Ethics. 2

National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. Disclosure of Research Information under the Freedom of Information Act: Report and Recommendations, April 8, 1977. 2

National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. Belmont Paper: Ethical Principles for Research Involving Human Subjects. April 1, 1977. 2

National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research. Research with Institutionalized Mentally Infirm Subjects: Recommendations. August 5, 1977. 2

United States Congress. PL93-348: National Research Act, Title II. 2

United States Congress. PL93-579: Privacy Act. 2

United States Department of Health, Education, and Welfare. Protection of Human Subjects: Technical Amendments. FR March 13, 1975, Vol. 40, No. 50, Pt. II. 2

United States Office of Management and Budget. Race and ethnic standards for federal statistics and administrative reporting, by K. K. Wallman & J. Hodgdon, July 1977. 2

United States. Executive Office of the President. Office of the President. Office of Science and Technology. Protection of Human Subjects. 2

American Nurses' Association. Human Rights Guidelines for Nurses in Clinical and Other Research, 1975. 1

American Occupational Therapy Association. Principles

of Occupational Therapy Ethics. 1

American Personnel and Guidance Association. Ethical Standards. Washington, D.C.: Author, 1974. 1

American Sociological Association. Code of Ethics, September 1, 1971. 1

Declaration of Helsinki. 1

Educational Testing Service. Guidelines on Obtaining Informed Consent. 1

Educational Testing Service. Policies and Procedural Guidelines for Control of Confidentiality of Data. October 1974. 1

Nuremberg Code. 1

United Cerebral Palsy Association. Research and Ethical Foundation. Research Grants. 1

United States Constitution. First, Fourth, Fifth, Eighth Ninth, and Fourteenth Amendments. 1

United States Constitution. Judicial decisions. 1

United States Constitution. Judicial decision: Willowbrook Consent Judgment. 1

United States Constitution. Judicial decision: Kaimowitz. 1

United States Congress. PL93-353: Title I, Health Services Research and Evaluation: Health Statistics. 1

United States Congress. PL93-502: Freedom of Information Act. 1

United States Congress. PL94-103: Developmentally Disabled Assistance and Bill of Rights Acts. 1

United States Bureau of the Census. Confidentiality of statistical and research data. Statistical Reporter, January 1977. 1

ICF/MR Certification. 1

Consumer group review (not otherwise endorsed). 1

Written consent of individual, parent or guardian (not otherwise endorsed). 1